# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

21 Jul 2026

## A clinical trial to evaluate using electroporation system for treatment purposes and drug delivery to the tumor

### Protocol summary

**Study aim**
Achieving optimized parameters for cancer treatment by electroporation method

**Design**
Patients are referred individually by specialist physicians according to the stated criteria for admission to the study and are treated by placing one or more needles around the tumor and stimulating the electroporation method. 40 patients are now ready to receive treatment in the hospital. Patients are aware of their treatment and the study is not capable of blinding.

**Settings and conduct**
After introducing the patient to this research and obtaining informed consent according to the patient's medical records and the location and type of tumor, the treatment protocol and the choice of reversible electroporation or electrochemotherapy should be selected. Then the type of electrodes, the number of stimulation doses of the drug required for complete treatment of the tumor is calculated. Then the electrodes are placed around the tumor and stimulation is performed according to the performed calculations.

**Participants/Inclusion and exclusion criteria**
Eligibility criteria: • Radiological based on cancer in Stages IA, IB, IIA, IIB, IIIA, IIIB, IV • Good performance (Karnofsky Score ≥ 70) • Life expectancy of at least 3 months Exclusion criteria: • Pregnancy Coagulation disorder (INR more than 1.5 times control) • Platelets less than 100,000 • Anemia (hemoglobin less than 10) • Serious acute infection • Having an implanted pacemaker, defibrillator or deep brain stimulator or heart arrhythmias.

**Intervention groups**
1) The intervention group received electroporation in addition to the usual treatment 2) control group with usual treatment

**Main outcome variables**
Changes of tumors' size, alteration in microscopic and pathological characteristics and IHC markers of the tumor, changes in clinical manifestations, changes of different serum markers.

### General information

**Reason for update**

**Acronym**
EP

**IRCT registration information**
IRCT registration number: **IRCT20190904044697N8**
Registration date: **2022-10-02, 1401/07/10**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-02, 1401/07/10**
Update count: **0**

**Registration date**
2022-10-02, 1401/07/10

**Registrant information**

**Name**
Mohammad Abdolahad

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 8802 8367

**Email address**
m.abdolahad@ut.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-10-01, 1401/07/09

**Expected recruitment end date**
2024-09-30, 1403/07/09

**Actual recruitment start date**
empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A clinical trial to evaluate using electroporation system for treatment purposes and drug delivery to the tumor

**Public title**

Cancer treatment by electroporation method

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Cancer patients who have different types of cancer with solid tumors. cancer stage IA, IB, IIA, IIB, IIIA, IIIB, IV (Karnofsky Score ≥ ۷۰) Patients with different types of benign and malignant tumors

**Exclusion criteria:**

Pregnancy Coagulation disorder (INR more than 1.5 times control) Platelets less than 100,000 Anemia (hemoglobin less than 10) Serious acute infection Having an implanted pacemaker, defibrillator or deep brain stimulator or cardiac arrhythmias.

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

In the irreversible electroporation method, we only need to place one or more needles in the desired area and around the tumor, and after placing these needles, 80 to 100 pulses with a duration of 100 microseconds will be applied and finally the needles will be removed. In the reversible electroporation method, the chemotherapy drug, whose dosage and possibility of use have been checked before, is injected as IT or IV. 5 to 15 minutes after drug injection, it will be possible to apply stimulation, so during this time, we will place the electrodes in the right place and after this time, we will apply electrical pulses. Applying the pulse increases the permeability of the cell membrane and the cell will receive a much higher dose than usual. For example, according to reports, the penetration of bleomycin has increased up to 5000 times.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Research ethics committees of Imam Khomeini hospital complex-Tehran University of Medical Sciences

**Street address**

North Amirabad - North Kargar Street - Above Jalal Al Ahmad Blvd - Opposite 9th Alley - Technical Faculty of Tehran University - Old building of Faculty of Electrical Engineering - Nanobioelectronics Laboratory

**City**

Tehran

**Province**

Tehran

**Postal code**

۵۱۵-۱۴۳۹۵

**Approval date**

2022-08-30, 1401/06/08

**Ethics committee reference number**

IR.TUMS.IKHC.REC.1401.125

## Health conditions studied

### 1

**Description of health condition studied**

Malignant cancer with solid tumor

**ICD-10 code**

C50

**ICD-10 code description**

Malignant neoplasm of breast

### 2

**Description of health condition studied**

Benign tumor with solid mass

**ICD-10 code**

D24

**ICD-10 code description**

Benign neoplasm of breast

### 3

**Description of health condition studied**

Malignant cancer with solid tumor

**ICD-10 code**

C22

**ICD-10 code description**

Malignant neoplasm of liver and intrahepatic bile ducts

### 4

**Description of health condition studied**

Benign tumor with solid mass

**ICD-10 code**

D13.4

**ICD-10 code description**

Benign neoplasm of liver

**5**

**Description of health condition studied**

Malignant cancer with solid tumor

**ICD-10 code**

C77

**ICD-10 code description**

Secondary and unspecified malignant neoplasm of lymph nodes

**6**

**Description of health condition studied**

Malignant cancer with solid tumor

**ICD-10 code**

C78.0

**ICD-10 code description**

Secondary malignant neoplasm of lung

**7**

**Description of health condition studied**

Malignant cancer with solid tumor

**ICD-10 code**

C79.2

**ICD-10 code description**

Secondary malignant neoplasm of skin

**8**

**Description of health condition studied**

Malignant cancer with solid tumor

**ICD-10 code**

C73

**ICD-10 code description**

Malignant neoplasm of thyroid gland

**9**

**Description of health condition studied**

Malignant cancer with solid tumor

**ICD-10 code**

C56

**ICD-10 code description**

Malignant neoplasm of ovary

**10**

**Description of health condition studied**

Malignant cancer with solid tumor

**ICD-10 code**

C48

**ICD-10 code description**

Malignant neoplasm of retroperitoneum and peritoneum

**11**

**Description of health condition studied**

Malignant cancer with solid tumor

**ICD-10 code**

C22.1

**ICD-10 code description**

Intrahepatic bile duct carcinoma

**12**

**Description of health condition studied**

Malignant cancer with solid tumor

**ICD-10 code**

C18

**ICD-10 code description**

Malignant neoplasm of colon

**13**

**Description of health condition studied**

Malignant cancer with solid tumor

**ICD-10 code**

C15

**ICD-10 code description**

Malignant neoplasm of esophagus

## Primary outcomes

**1**

**Description**

tumor size

**Timepoint**

Every two weeks

**Method of measurement**

Imaging modalities (Conventional ultrasound and especially Doppler ultrasound, MRI and CT scan)

**2**

**Description**

Clinical and quality of life changes

**Timepoint**

Every week

**Method of measurement**

Investigating of Clinical Manifestation

**3**

**Description**

Tumor cell death

**Timepoint**

every three month

**Method of measurement**

Immunostaining, Immunohistochemistry, H&E

**4**

**Description**

Metastasis to other organs

**Timepoint**

Every 6 month

**Method of measurement**

Imaging by MRI, CT or PET scan

## Secondary outcomes

### 1

**Description**
Quality Of Life
**Timepoint**
90 days
**Method of measurement**
Questionnaire about quality of life indicators based on EORTC QLQ-C30

## Intervention groups

### 1

**Description**
ABC Intervention group: Receiving electroporation in addition to the usual treatment. Definition of intervention: In cases where the tumor is inoperable, the patient will be assigned in the intervention group and will be treated with electroporation technique under the supervision of the surgeon in the following two cases: 1) Tumor through the skin can receive the electroporation technique and does not require open surgery. 2) In order to reach the tumor site, before receiving the electroporation technique, surgery should be performed to access the tumor and then the technique should be performed for the patient during the operation. In each treatment group, the patients received bleomycin with a dose of 1000 IU/ml and manufactured by the company. BDR Pharmaceuticals India and intravenously or intratumorally, eight minutes before electroporation. Then, electric pulses are inserted into the tumoral tissue through electrodes made of 316 stainless steel, which are biocompatible and have a medical grade, and with a thickness of 300 micrometers, which are either needles or plates, depending on the size of the tumor and the discretion of the study leader. Establishing electric pulses with a field intensity of 100 V/cm to 2000 V/cm and with a width of 1 to 100 microseconds and an alternating number of pulses will create holes in the cell membrane to increase the permeability of bleomycin. The pulse generating device is made in Iran by Nano Hesgarsazan Salamat Arya Company.
**Category**
Treatment - Devices

### 2

**Description**
Control group: In this group, patients receive only the standard and routine treatment prescribed by a specialist doctor.
**Category**
Treatment - Devices

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Imam Khomeini Hospital
**Full name of responsible person**
Mohammad Abdolahad
**Street address**
Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran
**City**
tehran
**Province**
Tehran
**Postal code**
۱۴۱۹۷۳۳۱۴۱
**Phone**
+98 21 2282 4069
**Email**
m.abdolahad@ut.ac.ir
**Web page address**

### 2

**Recruitment center**
**Name of recruitment center**
Shohadaye Tajrish Hospital
**Full name of responsible person**
Mohammad Abdolahad
**Street address**
Tajrish Square - Tajrish Martyrs Hospital
**City**
Tehran
**Province**
Tehran
**Postal code**
19899 34148
**Phone**
+98 21 25719
**Email**
m.abdolahad@ut.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Iran Nano Fund
**Full name of responsible person**
Dr Mohammad Hosein Bahreini
**Street address**
No. 38, West Nastaran Ave (Arab), Khorramshahr St., North Sohrevardi St., Tehran
**City**
Tehran
**Province**
Tehran
**Postal code**
1533984611
**Phone**
+98 21 8876 9188
**Email**
info@nanofund.ir
**Web page address**

http://nanofund.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran Nano Fund

**Proportion provided by this source**

70

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Other

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Abdolahad

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

electrotechnical Specialist in oncosurgery and cancer therapy

**Street address**

Nano bio electronic lab, ground floor, school of electrical and computer engineering, university of Tehran faculty of engineering, North Kargar Ave.

**City**

tehran

**Province**

Tehran

**Postal code**

1439957131

**Phone**

+98 21 8802 8367

**Email**

m.abdolahad@ut.ac.ir

**Web page address**

https://nbel.ut.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Abdolahad

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

electrotechnical Specialist in oncosurgery and cancer therapy

**Street address**

Nano bio electronic lab, ground floor, school of electrical and computer engineering, university of Tehran faculty of engineering, North Kargar Ave.

**City**

tehran

**Province**

Tehran

**Postal code**

1439957131

**Phone**

+98 21 8802 8367

**Email**

m.abdolahad@ut.ac.ir

**Web page address**

https://nbel.ut.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Abdolahad

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

electrotechnical Specialist in oncosurgery and cancer therapy

**Street address**

Nano bio electronic lab, ground floor, school of electrical and computer engineering, university of Tehran faculty of engineering, North Kargar Ave.

**City**

tehran

**Province**

Tehran

**Postal code**

1439957131

**Phone**

+98 21 8802 8367

**Email**

m.abdolahad@ut.ac.ir

**Web page address**

https://nbel.ut.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

60% of the information about the main outcome, can be shared

**When the data will become available and for how long**

Available 6 months after the paper has been published.

**To whom data/document is available**

The data will be available for medical staff and academic institutions.

**Under which criteria data/document could be used**

Non-identifiable personal data will not be usable for the applicant and will only inform the patient of a positive clinical trial that the device is functioning properly

**From where data/document is obtainable**

Applicants can request data access via email. The data will be available to the applicant in a categorized manner with pathology reports, imaging reports and serum markers by request.

**What processes are involved for a request to access data/document**

The data will be sent to the applicant within two weeks after the request.

**Comments**